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Patent Counsel
PHONE: 904-443-3074
FAX #: 904-443-3078
Re: Serial No. 10/027,579
Our Ref.: VTN571

Appeal Brief.

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DOCKET NO. VTN571

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Frank Molock, et al.

Serial No.: 10/027,579

Art Unit: 1732

Filed : December 20, 2001

Examiner: VARGOT, Mathieu

For : **COLORANTS FOR USE IN TINTED CONTACT LENSES AND
METHODS FOR THEIR PRODUCTION**

I hereby certify that this correspondence is being facsimile transmitted
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July 15, 2005

(Date)

JUL 15 2005

Linda Long

Name of applicant, assignee, or Registered Representative

/Linda Long/

(Signature)

July 15, 2005

(Date of Signature)

AUTHORIZATION TO CHARGE DEPOSIT ACCOUNT

Mail Stop Appeal
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Attached is an Appeal Brief for the above-captioned patent application.

Please charge Deposit Account No. 10-0750/VTN571/KAH in the name of Johnson & Johnson in the amount of \$320.00, representing the cost of filing a Brief on Appeal in the above-captioned matter.

The Commissioner is hereby authorized to charge any additional fees which may be required to Account No. 10-0750/VTN571/KAH. This Authorization is being submitted in triplicate.

Respectfully submitted,

/Karen A. Harding/

Karen A. Harding
Attorney for Applicant(s)
Reg. No. 33967

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(904) 443-3074
DATED: July 15, 2005

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(904) 443-3074
DATED: July 15, 2005

Docket No. VTN 571

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Frank F. Molock

Serial No.:10/027,579

Group Art Unit: 1732

Filed: December 20, 2001

Examiner: VARGOT, Matthieu

Title: COLORANTS FOR USE IN TINTED CONTACT LENSES AND METHODS FOR THEIR PRODUCTION

ATTENTION: BOARD OF PATENT APPEALS AND INTERFERENCES

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This brief is transmitted in triplicate. (37 CFR 1.192(a))

This brief contains these items under the following headings, and in the order set forth below (37 CFR 1.192(c)):

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Appellants' Brief for
USSN 10/027,579
Page - 2 -

TABLE OF CONTENTS

1.	REAL PARTY INTEREST	3
2.	RELATED APPEALS AND INTERFERENCES.....	3
3.	STATUS OF CLAIMS	3
4.	STATUS OF AMENDMENTS	3
5.	SUMMARY OF INVENTION	3
6.	STATEMENT OF ISSUES	4
7.	GROUPING OF CLAIMS	4
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Appellants' Brief for
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Page - 3 -

1. REAL PARTY INTEREST

The real party in interest of the subject patent application is Johnson & Johnson Visioncare, Inc, having a principal place of business at 7500 Centurion Parkway, Suite 100, Jacksonville FL 32256.

2. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences pending.

3. STATUS OF CLAIMS

Claims 24-26, 29, 30 and 41-43 are pending. Claims 1 through 23 and 31 through 40 have been withdrawn. Claims 27 and 28 have been canceled.

Claims 25-30 and 41 stand rejected under 35 U.S.C. 112.

Claims 24-30 and 41-43 stand rejected under 35 U.S.C. 103(a) in view of US 6,537,040 (Thakrar, et al).

4. STATUS OF AMENDMENTS

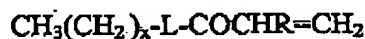
The claims were amended on July 16, 2004 and February. Applicants believe that all amendments have been entered.

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The present invention as recited in the pending claims is related to a method for manufacturing a tinted contact lens comprising the steps of: a.) applying to a molding surface of a mold a tinting-effective amount of a colorant comprising one or more pigments, one or more solvents and specifically recited binding polymers; b.) dispensing a lens-forming

Appellants' Brief for
USSN 10/027,579
Page - 4 -

amount of a lens material into the mold; c.) swelling the colorant in the lens material; and d.) curing the lens material in the mold to form the tinted contact lens, wherein the binding polymer and the lens material form an interpenetrating polymer network. Claim 24 recites binding polymers comprising copolymers of methacrylic acid and 2-hydroxyethyl methacrylate having a molecular weight of 7,000 to 100,000. Claim 42 recites a binding polymer comprising at least one hydrophobically-modified monomer selected from the group consisting of amides and esters of the formula:



Claim 43 recites a binding polymer comprising a homopolymer of 2-hydroxyethyl methacrylate having a molecular weight of about 7,000 to about 100,000.

6. STATEMENT OF ISSUES

Whether claims 25-30 and 41 are indefinite under 35 U.S.C. 112.

Whether claims 24-26, 29, 30 and 41-43 are patentable under 35 U.S.C. 103 over US 6,337,040, (Thakrar, et al.).

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For the purpose of the appeal, the claims 34-36, 29, 30, 41 and 43 stand or fall together. Claim 42 stands apart. Claims 29 and 30 stand apart.

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Claims 25-30 and 41 are definite under 35 U.S.C. 112

Examiner had rejected claims 25-30 and 41 and indefinite under 35 U.S.C. 112 in the November 17, 2004 final rejection. Applicants amended claim 25 in the February 17, 2005 amendment. However, upon further review in preparing this brief, it appears the rejection of

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Page - 5 -

claim 25 was not appropriate. Claim 25 as originally drafted recites that "the *lens material* comprises HEMA based hydrogels or silicone-based hydrogels". [emphasis added]. Since no specific lens material is recited in claim 24, and claim 25 recites specific lens materials, claim 25 is definite as originally drafted. It is respectfully requested that the amendment of claim 25 not be entered. Claim 25 in the Appendix of Claims includes the amendments made on February 17, 2005.

Claim 26 was also amended and claims 27 and 28 canceled in the February 17, 2005 amendment. The advisory action mailed on March 16, 2005 states that the reply was entered, but does not state whether the amendments were entered or whether the rejections based upon 35 U.S.C. 112 have been withdrawn. Applicants respectfully request confirmation that the amendment to claim 26 have been entered and claims 27 and 28 have been canceled.

No basis for rejecting claims 29, 30 and 41 under 35 U.S.C. 112 were given in the November 17, 2005 rejection, and claims 29, 30 and 41 do not appear to be indefinite. Applicants respectfully request confirmation that the rejection of these claims under 35 U.S.C. 112 have been withdrawn.

Claims 24-26, 29, 30 and 41-43 are patentable under 35 U.S.C. 103 over Thakrar, et al.

The present invention relates to a process for producing a colored contact lens using a binding polymer comprising one of three specifically defined polymers:

- copolymers of methacrylic acid and 2-hydroxyethyl methacrylate having a molecular weight of 7,000 to 100,000 (claim 24);
- polymer comprising at least one hydrophobically-modified monomer selected from the group consisting of amides and esters of the formula:
 - $\text{CH}_3(\text{CH}_2)_x\text{-L-COCHR=CH}_2$ (claim 42)

Appellants' Brief for
USSN 10/027,579

Page - 6 -

- a homopolymer of 2-hydroxyethyl methacrylate having a molecular weight of about 7,000 to about 100,000 (claim 43).

Thakrar et al. discloses producing a soft hydrogel colored contact lens via dispersing a coloring material in a carrier system which is compatible with the monomer material used to form the lens. Polymers comprising the amides and esters recited in the present claim 42 are neither disclosed nor suggested in Thakrar. Claim 42, is accordingly patentable over Thakrar et al.

Claims 24 and 43 respectively recite a 2-hydroxyethyl methacrylate copolymer and homopolymer having a molecular weight of 7,000 to 100,000.

Thakrar et al. is absolutely silent as to what molecular weight should be used to make a binding polymer containing 2-hydroxyethyl methacrylate, as recited in claims 24 and 43. The only disclosure or suggestion of the importance of molecular weight of the binding polymer came from the Applicants specification.

The Examiner rejected claims 24-36 and 41-43 as obvious in view of Thakrar (US 6,337,040) stating "one of ordinary skill in the art would have been able to pick and choose suitable resins and molecular weights from the resins generally taught in Thakrar et al". Page 3, November 17, 2004 rejection. Applicants respectfully disagree. Given the teaching of Thakrar, one of skill in the art would not have been directed to select any particular molecular weight. When polyHEMA which was commercially available at the time (300,000 MW from Aldrich, copy of page from Aldrich 2000-2001 catalog attached to Declaration of Dr. Douglas Vanderlaan, July 16, 2004) was used, the polyHEMA could not be dissolved in any of the solvents used in the Thakrar examples (1-butanol, 1-methoxy-2-propylacetate/cyclohexanone, cyclohexanone/methyl ethyl ketone, butoxy ethyl acetate). Based upon Thakrar et al. one of skill in the art might try other solvents (see column 3, lines 57-62), but there is no suggestion in Thakrar et al. to use poly(HEMA) of the molecular

Appellants' Brief for

USSN 10/027,579

Page - 7 -

weight recited in the claims. The only suggestion to try molecular weights in the claimed range comes from the present application.

Applicants also note that claims 29 and 30 require two medium boiling solvents and one low boiling solvent. The low boiling solvent decreases the viscosity of the binding polymer solution. Mixtures of solvents, let alone the two medium/one low boiling point solvent mixtures are neither disclosed nor suggested by Thrakrar. Accordingly, Applicants submit that claims 29 and 30 are patentable over Thrakrar.

Reversal of the rejections is respectfully requested.

8.5 CONCLUSION

For the foregoing reasons, the reversal of the rejections relating to claims 24-26, 29, 30 and 41-43 are respectfully requested.

9. APPENDIX OF CLAIMS INVOLVED IN THE APPEAL

(See attached)

Respectfully submitted,

/Karen A. Harding/
Karen A. Harding
Reg. No. 33,967
Date: July 15, 2005

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933
(904)-443-3074

Appellants' Brief for
USSN 10/027,579
Page - 8 -

APPENDIX OF CLAIMS INVOLVED IN THE APPEAL

24. A method for manufacturing a tinted contact lens comprising the steps of: a.) applying to a molding surface of a mold a tinting-effective amount of a colorant comprising one or more pigments, one or more solvents and a binding polymer having a molecular weight of about 7,000 to about 100,000 and comprising a copolymer of methacrylic acid and 2-hydroxyethyl methacrylate.; b.) dispensing a lens-forming amount of a lens material into the mold; c.) swelling the colorant in the lens material; and d.) curing the lens material in the mold to form the tinted contact lens, wherein the binding polymer and the lens material form an interpenetrating polymer network.
25. The method of claim 24, wherein the binding polymer has a molecular weight of about 7,000 to about 40,000 and the lens material optionally further comprises polymer units derived from silicone monomers.
26. The method of claim 24, wherein the binding polymer further comprises polymer units derived from lauryl methacrylate.
29. The method of claim 24 or 25, wherein the one or more solvents comprises two medium boiling point solvents and one low boiling point solvent.
30. The method of claim 29, wherein the two medium boiling point solvents comprise 1-ethoxy-2-propanol and isopropyl lactate.
41. The method of claim 24 wherein said pigment is coated or wetted with said binding polymer.

Appellants' Brief for
USSN 10/027,579

Page - 9 -

42. A method for manufacturing a tinted contact lens comprising the steps of: a.) applying to a molding surface of a mold a tinting-effective amount of a colorant comprising one or more pigments, one or more solvents and a binding polymer comprising at least one hydrophobically-modified monomer selected from the group consisting of amides and esters of the formula:



wherein L is selected from -NH or oxygen, x is a whole number from 2 to 24, R is selected from the group consisting of C₁ to C₆ alkyl or hydrogen; b.) dispensing a lens-forming amount of a lens material into the mold; c.) swelling the colorant in the lens material; and d.) curing the lens material in the mold to form the tinted contact lens, wherein the binding polymer and the lens material form an interpenetrating polymer network.

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Docket No. VTN 571

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Frank F. Molock

Serial No.:10/027,579

Group Art Unit: 1732

Filed: December 20, 2001

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Appellants' Brief for
USSN 10/027,579
Page - 2 -

TABLE OF CONTENTS

1.	REAL PARTY INTEREST	3
2.	RELATED APPEALS AND INTERFERENCES.....	3
3.	STATUS OF CLAIMS	3
4.	STATUS OF AMENDMENTS	3
5.	SUMMARY OF INVENTION	3
6.	STATEMENT OF ISSUES	4
7.	GROUPING OF CLAIMS	4
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Appellants' Brief for
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Page - 3 -

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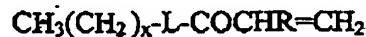
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Page - 4 -

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Page - 9 -

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Appellants' Brief for
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Page - 2 -

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Page - 3 -

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Claims 24-30 and 41-43 stand rejected under 35 U.S.C. 103(a) in view of US 6,337,040 (Thakrar, et al).

4. STATUS OF AMENDMENTS

The claims were amended on July 16, 2004 and February. Applicants believe that all amendments have been entered.

5. SUMMARY OF INVENTION

The present invention as recited in the pending claims is related to a method for manufacturing a tinted contact lens comprising the steps of: a.) applying to a molding surface of a mold a tinting-effective amount of a colorant comprising one or more pigments, one or more solvents and specifically recited binding polymers; b.) dispensing a lens-forming

Appellants' Brief for
USSN 10/027,579
Page - 4 -

amount of a lens material into the mold; c.) swelling the colorant in the lens material; and d.) curing the lens material in the mold to form the tinted contact lens, wherein the binding polymer and the lens material form an interpenetrating polymer network. Claim 24 recites binding polymers comprising copolymers of methacrylic acid and 2-hydroxyethyl methacrylate having a molecular weight of 7,000 to 100,000. Claim 42 recites a binding polymer comprising at least one hydrophobically-modified monomer selected from the group consisting of amides and esters of the formula:



Claim 43 recites a binding polymer comprising a homopolymer of 2-hydroxyethyl methacrylate having a molecular weight of about 7,000 to about 100,000.

6. STATEMENT OF ISSUES

Whether claims 25-30 and 41 are indefinite under 35 U.S.C. 112.

Whether claims 24-26, 29, 30 and 41-43 are patentable under 35 U.S.C. 103 over US 6,337,040, (Thakrar, et al.).

7. GROUPING OF CLAIMS

For the purpose of the appeal, the claims 34-36, 29, 30, 41 and 43 stand or fall together. Claim 42 stands apart. Claims 29 and 30 stand apart.

8. ARGUMENTS

Claims 25-30 and 41 are definite under 35 U.S.C. 112

Examiner had rejected claims 25-30 and 41 and indefinite under 35 U.S.C. 112 in the November 17, 2004 final rejection. Applicants amended claim 25 in the February 17, 2005 amendment. However, upon further review in preparing this brief, it appears the rejection of

Appellants' Brief for
USSN 10/027,579

Page - 5 -

claim 25 was not appropriate. Claim 25 as originally drafted recites that "the *lens material* comprises HEMA based hydrogels or silicone -based hydrogels". [emphasis added]. Since no specific lens material is recited in claim 24, and claim 25 recites specific lens materials, claim 25 is definite as originally drafted. It is respectfully requested that the amendment of claim 25 not be entered. Claim 25 in the Appendix of Claims includes the amendments made on February 17, 2005.

Claim 26 was also amended and claims 27 and 28 canceled in the February 17, 2005 amendment. The advisory action mailed on March 16, 2005 states that the reply was entered, but does not state whether the amendments were entered or whether the rejections based upon 35 U.S.C. 112 have been withdrawn. Applicants respectfully request confirmation that the amendment to claim 26 have been entered and claims 27 and 28 have been canceled.

No basis for rejecting claims 29, 30 and 41 under 35 U.S.C. 112 were given in the November 17, 2005 rejection, and claims 29, 30 and 41 do not appear to be indefinite. Applicants respectfully request confirmation that the rejection of these claims under 35 U.S.C. 112 have been withdrawn.

Claims 24-26, 29, 30 and 41-43 are patentable under 35 U.S.C. 103 over Thakrar, et al.

The present invention relates to a process for producing a colored contact lens using a binding polymer comprising one of three specifically defined polymers:

- copolymers of methacrylic acid and 2-hydroxyethyl methacrylate having a molecular weight of 7,000 to 100,000 (claim 24);
- polymer comprising at least one hydrophobically-modified monomer selected from the group consisting of amides and esters of the formula:
 - $\text{CH}_3(\text{CH}_2)_x\text{-L-COCHR=CH}_2$ (claim 42)

Appellants' Brief for
USSN 10/027,579

Page - 6 -

- a homopolymer of 2-hydroxyethyl methacrylate having a molecular weight of about 7,000 to about 100,000 (claim 43).

Thakrar et al. discloses producing a soft hydrogel colored contact lens via dispersing a coloring material in a carrier system which is compatible with the monomer material used to form the lens. Polymers comprising the amides and esters recited in the present claim 42 are neither disclosed nor suggested in Thakrar. Claim 42, is accordingly patentable over Thakrar et al.

Claims 24 and 43 respectively recite a 2-hydroxyethyl methacrylate copolymer and homopolymer having a molecular weight of 7,000 to 100,000.

Thakrar et al. is absolutely silent as to what molecular weight should be used to make a binding polymer containing 2-hydroxyethyl methacrylate, as recited in claims 24 and 43. The only disclosure or suggestion of the importance of molecular weight of the binding polymer came from the Applicants specification.

The Examiner rejected claims 24-36 and 41-43 as obvious in view of Thakrar (US 6,337,040) stating "one of ordinary skill in the art would have been able to pick and choose suitable resins and molecular weights from the resins generally taught in Thakrar et al". Page 3, November 17, 2004 rejection. Applicants respectfully disagree. Given the teaching of Thakrar, one of skill in the art would not have been directed to select any particular molecular weight. When poly HEMA which was commercially available at the time (300,000 MW from Aldrich, copy of page from Aldrich 2000-2001 catalog attached to Declaration of Dr. Douglas Vanderlaan, July 16, 2004) was used, the poly HEMA could not be dissolved in any of the solvents used in the Thakrar examples (1-butanol, 1-methoxy-2-propylacetate/cyclohexanone, cyclohexanone/methyl ethyl ketone, butoxy ethyl acetate). Based upon Thakrar et al. one of skill in the art might try other solvents (see column 3, lines 57-62), but there is no suggestion in Thakrar et al. to use poly(HEMA) of the molecular

Appellants' Brief for

USSN 10/027,579

Page - 7 -

weight recited in the claims. The only suggestion to try molecular weights in the claimed range comes from the present application.

Applicants also note that claims 29 and 30 require two medium boiling solvents and one low boiling solvent. The low boiling solvent decreases the viscosity of the binding polymer solution. Mixtures of solvents, let alone the two medium/one low boiling point solvent mixtures are neither disclosed nor suggested by Thrakrar. Accordingly, Applicants submit that claims 29 and 30 are patentable over Thrakrar.

Reversal of the rejections is respectfully requested.

8.5 CONCLUSION

For the foregoing reasons, the reversal of the rejections relating to claims 24-26, 29, 30 and 41-43 are respectfully requested.

9. APPENDIX OF CLAIMS INVOLVED IN THE APPEAL

(See attached)

Respectfully submitted,

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Appellants' Brief for
USSN 10/027,579
Page - 8 -

APPENDIX OF CLAIMS INVOLVED IN THE APPEAL

24. A method for manufacturing a tinted contact lens comprising the steps of: a.) applying to a molding surface of a mold a tinting-effective amount of a colorant comprising one or more pigments, one or more solvents and a binding polymer having a molecular weight of about 7,000 to about 100,000 and comprising a copolymer of methacrylic acid and 2-hydroxyethyl methacrylate.; b.) dispensing a lens-forming amount of a lens material into the mold; c.) swelling the colorant in the lens material; and d.) curing the lens material in the mold to form the tinted contact lens, wherein the binding polymer and the lens material form an interpenetrating polymer network.
25. The method of claim 24, wherein the binding polymer has a molecular weight of about 7,000 to about 40,000 and the lens material optionally further comprises polymer units derived from silicone monomers.
26. The method of claim 24, wherein the binding polymer further comprises polymer units derived from lauryl methacrylate.
29. The method of claim 24 or 25, wherein the one or more solvents comprises two medium boiling point solvents and one low boiling point solvent.
30. The method of claim 29, wherein the two medium boiling point solvents comprise 1-ethoxy-2-propanol and isopropyl lactate.
41. The method of claim 24 wherein said pigment is coated or wetted with said binding polymer.

Appellants' Brief for
USSN 10/027,579

Page - 9 -

42. A method for manufacturing a tinted contact lens comprising the steps of: a.) applying to a molding surface of a mold a tinting-effective amount of a colorant comprising one or more pigments, one or more solvents and a binding polymer comprising at least one hydrophobically-modified monomer selected from the group consisting of amides and esters of the formula:



wherein L is selected from -NH or oxygen, x is a whole number from 2 to 24, R is selected from the group consisting of C₁ to C₆ alkyl or hydrogen; b.) dispensing a lens-forming amount of a lens material into the mold; c.) swelling the colorant in the lens material; and d.) curing the lens material in the mold to form the tinted contact lens, wherein the binding polymer and the lens material form an interpenetrating polymer network.

43. A method for manufacturing a tinted contact lens comprising the steps of: a.) applying to a molding surface of a mold a tinting-effective amount of a colorant comprising one or more pigments, one or more solvents and a binding polymer having a molecular weight of about 7,000 to about 100,000 and comprising a homopolymer of 2-hydroxyethyl methacrylate.; b.) dispensing a lens-forming amount of a lens material into the mold; c.) swelling the colorant in the lens material; and d.) curing the lens material in the mold to form the tinted contact lens, wherein the binding polymer and the lens material form an interpenetrating polymer network.